

REMARKS

Status of the Claims

Claims 4, 6-43, and 49-62 are pending. Pending claims 22-43, and 49-54 are currently withdrawn. Claim 55-62 are added. No new matter is added in the above amendment. Support for new claims 55-62 can be found in the Specification on pages 24-27.

Issues under 35 U.S.C. § 102

Pending claims 4, 6-8, 10-17, and 19-21 are rejected under 35 U.S.C. § 102(b), as being allegedly anticipated by Yu et al. This rejection is respectfully traversed. Reconsideration and withdrawal thereof are requested.

As stated in the record, Yu et al. describe the enzymatic conversion of arachidonyl ethanolamine (anandamide, AEA) to PGE₂-ethanolamide in cell lines expressing COX-2, but not COX-1.

The Yu et al. process contacts the cell with anandamide, measures the synthesis of PGE₂, and uses the measurement as an indication of COX-2. See the Yu et al. abstract:

Incubation of anandamide with lysates and the intact cell line expressing COX-2 but not that of COX-1 produced prostaglandin E₂ ethanolamide. These results demonstrate the existence of a COX-2 mediated pathway for anandamide metabolism, and the metabolites formed represent a novel class of prostaglandins.

In other words, they “test the ability of COX enzymes to metabolize AEA.” See p. 21183.

Yu et al. fail to disclose or suggest the claimed method of direct detection from a sample of a subject to determine an activity of a COX-2 enzyme.

Furthermore, Yu et al. fail to disclose or suggest a method whereby such direct detection from a sample of a subject, and quantification of the results is indicative of an activity of a COX-2 enzyme.

Yu et al. also fail to disclose or suggest the connection between PGE₂ to COX-2 activity, its presence, and the significance of its presence. Yu et al. also fail to disclose or suggest the claimed steps of relating the detected amounts to disease states. This should be clear by the statement of Yu et al. in the last paragraph, on page 21186: “At the present time the physiological significance of the metabolism of AEA by COX-2 is not known.”

The present invention provides significant advantages over the prior art, such as the ability to detect and/or quantify COX-2 directly in the patient of sample thereof.

Applicants respectfully submit that in view of numerous deficiencies of the Yu et al. reference, including those discussed above, it is clear that the reference does not meet the legal standard of anticipation. Simply, the identical invention is not shown in Yu et al. in as complete detail as is contained in the claims.

Issues under 35 U.S.C. § 103

Claims 9 and 18 are rejected under 35 U.S.C. § 103(a) as allegedly be obvious over Stichtenoth et al. and Yu et al. This rejection is respectfully traversed. Reconsideration and withdrawal thereof are requested.

The deficiencies of Yu et al. are discussed in detail, above. The Stichtenoth et al. article, as is indicated in the office action, fails to remedy the deficiencies of Yu et al. This reference is apparently asserted based solely on its disclosure of the use of urine as an assay sample.

The Office Action fails to set forth why one of ordinary skill in the art would be motivated to, or if it would even be possible to, combine the steps of contacting the cell with anandamide, measuring the synthesis of PGE-E₂, and using the measurement as an indication of COX-2, with a urine collection step. There is no motivation to obtain the cell cultures of Yu et al. by means of a urine sample.

Additionally, the instantly rejected claims should now depend from allowed base claims. Since allowed base claim is free from prior art, the dependent claim, by its nature as a dependent claim, is free from prior art as well.

In view of the above, Applicants respectfully request that this rejection be withdrawn.

Interview Request

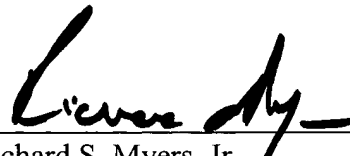
If the above response does not render the pending claims allowable, an interview with the Examiner is requested. The Yu et al. reference is known to Applicants. It is cited in the Specification, PTO Form 1449, and is discussed in these and the formerly submitted Remarks. The present invention is distinguished therefrom. Applicants believe that should any issues remain following this second response, and interview would help alleviate them.

If necessary, please contact the undersigned for a mutually convenient time.

From the foregoing, further and favorable reconsideration in the form of a Notice of Allowability is requested and such action is believed to be in order.

If the Examiner has any questions concerning this amendment or the application in general, he is requested to contact the undersigned at the number listed below.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Richard S. Myers, Jr.", is written over a horizontal line.

Richard S. Myers, Jr.
Registration No. 42,022
STITES & HARBISON
Customer No. 32885

Attorneys for Applicant
Telephone: (615) 782-2333